K081749

5.0 510(k) SUMMARY

SEP 30 2008

Submitter: Pentron Ceramics, Inc.
500 Memorial Drive
Somerset, NJ 08873
(732) 563-4755
(732) 563-1120 (fax)

Contact: Cindy Salter, QA/RA Manager

Date Prepared: June 14, 2008

Trade Name: Avante Z Zirconia $(AS)^3$ Blocks

Classification Name: Porcelain Powder for Clinical Use (872.6660)

Predicate Devices: IPS e.max ZirCAD by Ivoclar Vivadent AG (K051705)
Zeno Zr Disc by Wieland Dental+Technik Gmbh&Co KG (K073108)

Device Description: Avante Z Zirconia $(AS)^3$ Blocks are partially sintered yttria-stabilized zirconia blocks for use as CAD/CAM milling blanks. They are in a chalk-like state and can be milled using any compatible CAD/CAM machine such as Sirona InLab (Sirona Dental Systems, LLC, Charlotte, NC) or KaVO Everest (Ka Vo Dental, Lake Zurich, IL). It is necessary to mill the blocks with an enlargement factor to account for the shrinkage that occurs during sintering. After the block is milled, it is sintered which causes the material to densify into a high strength ceramic suitable for dental inlays, onlays, crowns, and bridges.

Intended Use: Avante Z Zirconia $(AS)^3$ Blocks consists of machinable zirconia blocks for the preparation of full ceramic crowns, onlays, and multi-unit bridges and inlay bridges (anterior and molar).

Technological Characteristics: All of the components of Avante Z Zirconia $(AS)^3$ Blocks have been used in legally marketed devices. The formulations have not been changed in any way that may adversely impact safety or efficacy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 3 0 2008

Ms. Cindy Salter
Quality Assurance/Regulatory Affairs
Pentron Ceramics, Incorporated
500 Memorial Drive
Somerset, New Jersey 08873

Re: K081749
Trade/Device Name: Avante Z Zirconia $(AS)^3$ Blocks
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder for Clinical Use
Regulatory Class: II
Product Code: EIH
Dated: September 19, 2008
Received: September 23, 2008

Dear Ms. Salter:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K081749

4.0 INDICATIONS FOR USE STATEMENT

Avante Z Zirconia (AS)^3 Blocks consists of machinable zirconia blocks for the preparation of full ceramic crowns, onlays, and multi-unit bridges and inlay bridges (anterior and molar).

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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